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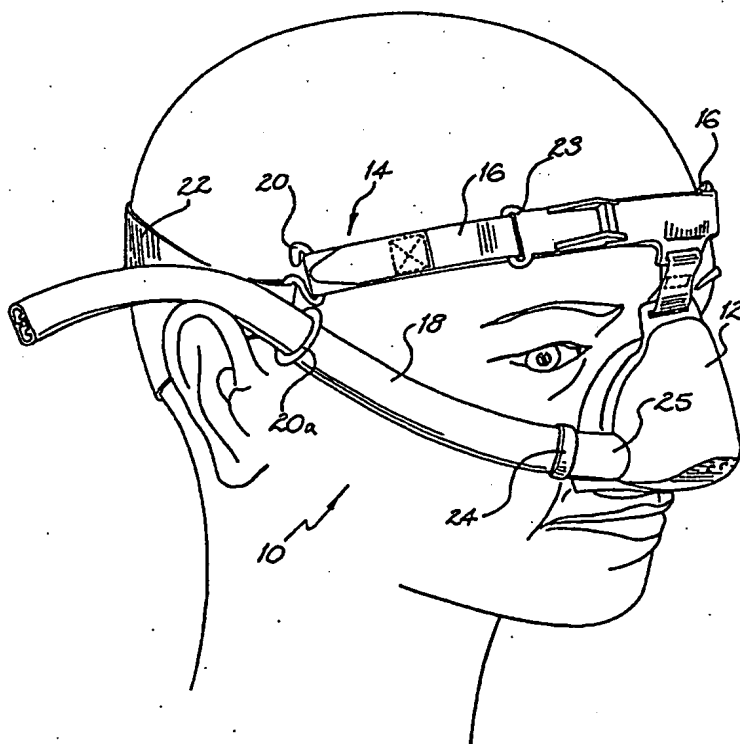
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(21) International Application Number: PCT/AU97/00822 (22) International Filing Date: 2 December 1997 (02.12.97) (30) Priority Data: PO 4002 2 December 1996 (02.12.96) AU (71) Applicant (for all designated States except US): RESMED LIMITED [AU/AU]; 82 Waterloo Road, North Ryde, NSW 2113 (AU). (72) Inventors; and (75) Inventors/Applicants (for US only): KWOK, Philip, Rodney [AU/AU]; 7 Apollo Avenue, West Pymble, NSW 2073 (AU). HELY, Kenneth, Frederick [AU/AU]; 50 Charles Place, Jannali, NSW 2226 (AU). BRUDERER, Jakob, Walter [AU/AU]; 6 Cottonwood Court, Woodbury Park, Tuggerah, NSW 2259 (AU). SULLIVAN, Colin, Edward [AU/AU]; 27 Whart Road, Birchgrove, NSW 2041 (AU). (74) Agent: SPRUSON & FERGUSON; G.P.O BOX 3898, Sydney, NSW 2001 (AU).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>

(54) Title: **A MASK AND HARNESS ASSEMBLY**

(57) Abstract

A mask and harness assembly (10). The assembly (10) includes a mask (12), a harness (14) including at least one strap (16) connected to the mask (12) and at least one fluid delivery tube (18) connected to, and in fluid communication with, the mask (12). The strap(s) (16) and the tube(s) (18) being adapted to locate the mask (12) at a predetermined location on the head of the wearer.



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A MASK AND HARNESS ASSEMBLY

Field of the Invention

The present invention relates to a mask and harness assembly.

5 The invention will be described with reference to a nasal mask located on the head of the wearer by a harness for the administration of continuous positive airway pressure (CPAP) treatment. However, it will be appreciated that the invention is not limited to this particular use and is equally suited for use with, for example, facemasks, nasal prongs or mouthmasks, and for treatments including assisted respiration or
10 mechanical ventilation.

Background of the Invention

Hitherto, masks have been located on a wearer's face by a harness formed from straps extending from the mask around the wearer's head and/or neck. A hollow
15 tube is generally attached to the mask, independent of the harness, to supply a breathable gas such as air to the wearer.

This arrangement has several disadvantages. Firstly, the tube is often inadvertently pulled by movement of the wearer, particularly during sleep, which can dislodge the mask and adversely affect gas delivery to the patient's airways, thereby
20 reducing treatment effectiveness.

Another disadvantage is that the mask, straps and tube are prone to entanglement which increases the difficulty of correctly installing the mask and harness.

The present invention seeks to overcome or at least ameliorate these problems with the prior art.

25

Summary of the Invention

The present invention provides a mask and harness assembly, the assembly includes a mask, a harness including at least one strap connected to the mask and at least one fluid delivery tube connected to, and in fluid communication with, the mask,

wherein the strap(s) and the tube(s) are adapted to locate the mask at a predetermined location on the head of the wearer.

Preferably, the harness includes three straps and one tube. In other configurations, the harness can include two straps and two tubes or one strap and three
5 tubes.

In an embodiment, a first end of two of the straps are connected to a lower portion of the mask and one of the straps and a first end of one fluid delivery tube are connected to an upper portion of the mask. In another embodiment, a first end of two of the straps are connected to an upper portion of the mask and a first end of one of the
10 straps and one fluid delivery tube are connected to a lower portion of the mask. In both these embodiments the harness includes a cap portion positioned, in use, on the rear of the wearer's skull to which a second end of the three straps and tube are connected.

In a further embodiment, the harness assembly includes one strap connected at each end to the mask and extending around the wearer's head and one tube connected to
15 the mask and the strap.

The tube is preferably crush resistant. Desirably, the tube is also flexible.

In another form, the tube is relatively rigid and is shaped to conform to the wearer's face over which it lies. The tube can also include an outer sheath to improve comfort.

20 In a preferred form, the tube includes an inner wall defining a passageway through which fluid can pass, and one or more inwardly directed ribs depending from the inner wall, and wherein, on inwardly-directed compression of the tube, the distal edge portion of one or more of said ribs engages an opposed portion of the tube inner wall to maintain said passageway at least partially open.

25 In a particularly preferred form, the one or more ribs are arranged to run along the longitudinal axis of the tube. The tube can have many cross-sectional shapes, and, in one advantageous form, is substantially rectangular having planar top and bottom portions and curved side portions. In such an arrangement, the ribs depend from the

top and/or bottom portions to, on upwardly or bottomwardly directed compression, engage the respective opposed top and/or bottom portion inner wall.

The tube is preferably coupled by a connector having a hollow male plug of complementary shape to said tube inner wall and adapted to be received therein. The plug terminates in a plenum chamber internal of the connector, the plenum chamber
5 being in communication with a socket that can be received into said mask or a port coupling of said mask.

Brief Description of the Drawings

10 Embodiments of the present invention will now be described with reference to the drawings in which:

Fig. 1 shows a perspective view of a mask and harness assembly in accordance with a first embodiment of the invention;

Fig. 2 shows a perspective view of a mask and harness assembly in accordance
15 with a second embodiment of the invention;

Fig. 3 shows a perspective view of a mask and harness assembly in accordance with a third embodiment of the invention;

Fig. 4 shows a crush resistant delivery tube used in the mask and harness assembly according to the invention;

20 Fig. 5 shows the tube of Fig. 4 in vertical cross-section;

Fig. 6 shows the tube of Fig. 5 when crushed;

Fig. 7 shows a double passage crush resistant delivery tube; and

Fig. 8 shows a coupling assembly for use of the delivery tube of Fig. 4 to a single bore tube or mask.

25

Detailed Description of Preferred Embodiments

Referring to Fig. 1, there is shown a first embodiment of a mask and harness assembly 10 according to the present invention. The assembly 10 includes a nose mask 12 and a harness, indicated generally at 14. The harness 14 includes left and right-hand

upper length adjustable straps 16, a right-hand lower length adjustable strap (not shown), and a left-hand fluid delivery tube 18. The straps and the tube extend from the mask to a yoke 20 attached to a semi-circular cap portion 22. The straps are connected to the mask 12 through apertures 23. The fluid delivery tube 18 is connected to, and in fluid communication with, the mask 12 by virtue of coupling 24 which engages a coupling port 25 extending from the mask.

The fluid delivery tube 18 acts in the manner of a strap and is length adjustable by virtue of its frictional engagement with a lower portion 20a of the yoke 20.

Fig. 2 shows a second embodiment of a mask and harness assembly according to the invention in which like reference numerals are used to indicate like features. In this second embodiment, the harness includes left and right lower length adjustable straps 26 (right hand not shown), an upper fluid delivery tube 27 and upper right-hand length adjustable strap 16.

Fig. 3 shows a third embodiment of a mask and harness assembly according to the invention in which a single length adjustable lower strap 28 extending from the mask and encircling the head is used in place of the dual lower straps and cap portion shown previously.

Fig. 4 shows a preferred form of fluid delivery tubing 18, 27. The tubing 18 is of substantially rectangular cross-section having flat top and bottom walls 32,34 and curved or rounded side walls 36,38. A passageway 40 through which gas to be delivered can pass is defined within the boundaries of the top, bottom and side walls 32-38.

As best can be seen from Figs. 5 and 6, depending downwardly from the top wall 32 is a longitudinally extending rib 42, and in a similar manner, upwardly directed ribs 44,46 depend from the bottom wall 34. Each rib is formed generally by a base and a distal edge portion. Fig. 5 shows a situation where the tubing 18 is in its normal state whereby the single passageway 40 is open to the flow of gas. As shown in Fig. 6, on a vertically directed compressional force, such as would occur on crushing or kinking, the top and bottom walls 32,34 deflect in the direction shown, resulting in the distal

edge portions ribs 42-46 respectively engaging an opposed portion of either the top or bottom walls respectively. The result is four separate passageways 48, 50, 52 and 54 in the vicinity of the region of crushing rather than the single passageway 40 in the uncrushed state. The reduction in cross-sectional area is represented by the area
5 between the distal edge portion of each of the ribs and the opposed respective top or bottom wall.

The substantially rectangular cross-sectional shape tends to avoid occlusion of the passageway 40 on the occurrence of laterally directed crushing, in that the passageway 40 would tend to become generally more circular in cross-sectional shape.

10 The embodiment shown has three depending ribs, however it is equally the case that any convenient number of ribs can be utilised, including a single rib.

The tube 18, 27, in the preferred form shown, is extruded from an elastomeric material of hardness nominally between 35 and 55 Shore A. In the use of the crush resistant fluid delivery tubing 18 for the purposes of CPAP treatment, it is preferable
15 that the reduction in internal cross-sectional area due to crushing be less than 40%, which allows for minimal disruption of flow rates and back pressure, thus maintaining therapeutic treatment pressures.

One particular preferred embodiment suitable for delivering air or breathable gas continuously at a pressure elevated above atmospheric pressure (viz., CPAP
20 treatment) has three internal ribs as shown in Figs. 4-6, the nominal dimensions are as follows: outside transverse peripheral "circumference" 22 mm, height 8.5 mm and a nominal wall thickness 1.75 mm. The internal cross-sectional area therefore is approximately 52 mm². This configuration is equivalent to a circular tube of internal diameter 8.0 mm. On compression, as shown in Fig. 6, the total internal cross-
25 sectional area becomes approximately 34 mm². This is equivalent to a circular tube having an internal diameter of 6.6 mm.

Fig. 7 shows another embodiment where there are two of the tubes 18, 27, in a vertical stacked arrangement lying within a unifying elastomeric sheath 60. Many other arrangements whereby a multiple number of tubes 18 can be arranged within a single

sheath can be provided. Advantages of such independent multiple tubes 18 are that a number of gases or liquids can be delivered without mixing, gases at different pressures can be delivered and/or one of the tubes can be used to provide a feedback signal of mask pressure to a control system.

5 Fig. 8 shows a coupling arrangement 24 between an end of the gas delivery tube 18, 27, previously described and a coupling port 25 of the mask 12. An intermediate connector 70 has an extending hollow male plug 72 of complementary shape to the inner walls defining the passageway 40 of the tube 18,27 to be received therein. The end portion of the tube 18,27 is received within a recess 74 formed by a
10 collar 76 of the connector 70. The plug 72 terminates into a chamber 78 that is received within the port 25. In another embodiment, an air vent insert 80 also is provided that has a socket 82 within which to receive the end of the connector 70 defining the chamber 78, and intermediate air venting region 82 and a flange 84 to be received within the mask port 25 at the other end. All couplings shown and described
15 are preferably achieved by means of a frictional fit, although non-toxic adhesives or mechanical fastenings such as clamps can be used if desired.

Further, if desired, the connector 70 and insert 80 can be omitted and the tube 18, 27 can be directly attached to the port 25.

Industrial Applicability

20 The invention simplifies mask and harness assembly construction by combining one of the straps and the fluid delivery tube into a single component.

In a preferred form, the tubing has a large frictional contact area with the head and thereby is more resistant to pulling, resulting in more secure mask placement in comparison to the independent tube configurations. The large contact area also reduces
25 the pressure of the tube on the wearer's face, thereby increasing wearer comfort.

Further, the substantially rectangular cross section of the preferred tubing is also comfortable and familiar to the wearer as it lays flat against the head in a similar manner to existing straps. Also, the low profile of the preferred tubing reduces the likelihood of the tube being inadvertently knocked or moved by the wearer.

Numerous alterations and modifications, as would be apparent to one skilled in the art, are to be considered as falling within the ambit of the present invention, embodiments of which have been hereinbefore described.

CLAIMS:

1. A mask and harness assembly, the assembly includes a mask, a harness including at least one strap connected to the mask and at least one fluid delivery tube connected to, and in fluid communication with, the mask, wherein the strap(s) and the tube(s) are adapted to locate the mask at a predetermined location on the head of the wearer.
2. An assembly as claimed in claim 1, wherein the harness includes three straps and one tube.
3. An assembly as claimed in claim 1, wherein the harness includes two straps and two tubes.
4. An assembly as claimed in claim 1, wherein the harness includes one strap and three tubes.
5. An assembly as claimed in claim 2, wherein a first end of two of the straps are connected to a lower portion of the mask and one of the straps and a first end of the fluid delivery tube are connected to an upper portion of the mask.
6. An assembly as claimed in claim 2, wherein a first end of two of the straps are connected to an upper portion of the mask and a first end of one of the straps and one fluid delivery tube are connected to a lower portion of the mask.
7. An assembly as claimed in claim 5 or 6, wherein the harness includes a cap portion positioned, in use, on the rear of the wearer's skull to which a second end each of the three straps and the tube are connected.
8. An assembly as claimed in claim 1, wherein the harness assembly includes one strap connected at each end to the mask and extending around the wearer's head and one tube connected to the mask and the strap.
9. An assembly as claimed in any one of the preceding claims, wherein the tube is crush resistant.

10. An assembly as claimed in any one of the preceding claims, wherein the tube has a low cross-sectional profile.

11. An assembly as claimed in any one of the preceding claims, wherein the tube is flexible.

5 12. An assembly as claimed in any one of claims 1 to 10, wherein the tube is relatively rigid and is shaped to conform to the wearer's face.

13. An assembly as claimed in any one of the preceding claims, wherein tube is covered by an outer sheath.

14. An assembly as claimed in any one of the preceding claims, wherein
10 the tube includes an inner wall defining a passageway through which fluid can pass, and one or more inwardly directed ribs depending from the inner wall, and wherein, on inwardly-directed compression of the tube, the distal edge portion of one or more of said ribs engages an opposed portion of the tube inner wall to maintain said passageway at least partially open.

15 15. An assembly as claimed in claim 14, wherein the one or more ribs are arranged to run along the longitudinal axis of the tube.

16. An assembly as claimed in claim 14 or 15, wherein the tube is substantially rectangular having planar top and bottom portions and curved side portions.

20 17. An assembly as claimed in claim 16, wherein the ribs depend from the top and/or bottom portions to, on upwardly or bottomwardly directed compression, engage the respective opposed top and/or bottom portion inner wall.

18. An assembly as claimed in any one of claims 14 to 17, wherein the tube is coupled by a connector having a hollow male plug of complementary shape to
25 said tube inner wall and adapted to be received therein, the plug terminating in a plenum chamber internal of the connector, the plenum chamber being in communication with a socket that can be received into said mask or a port coupling of said mask.

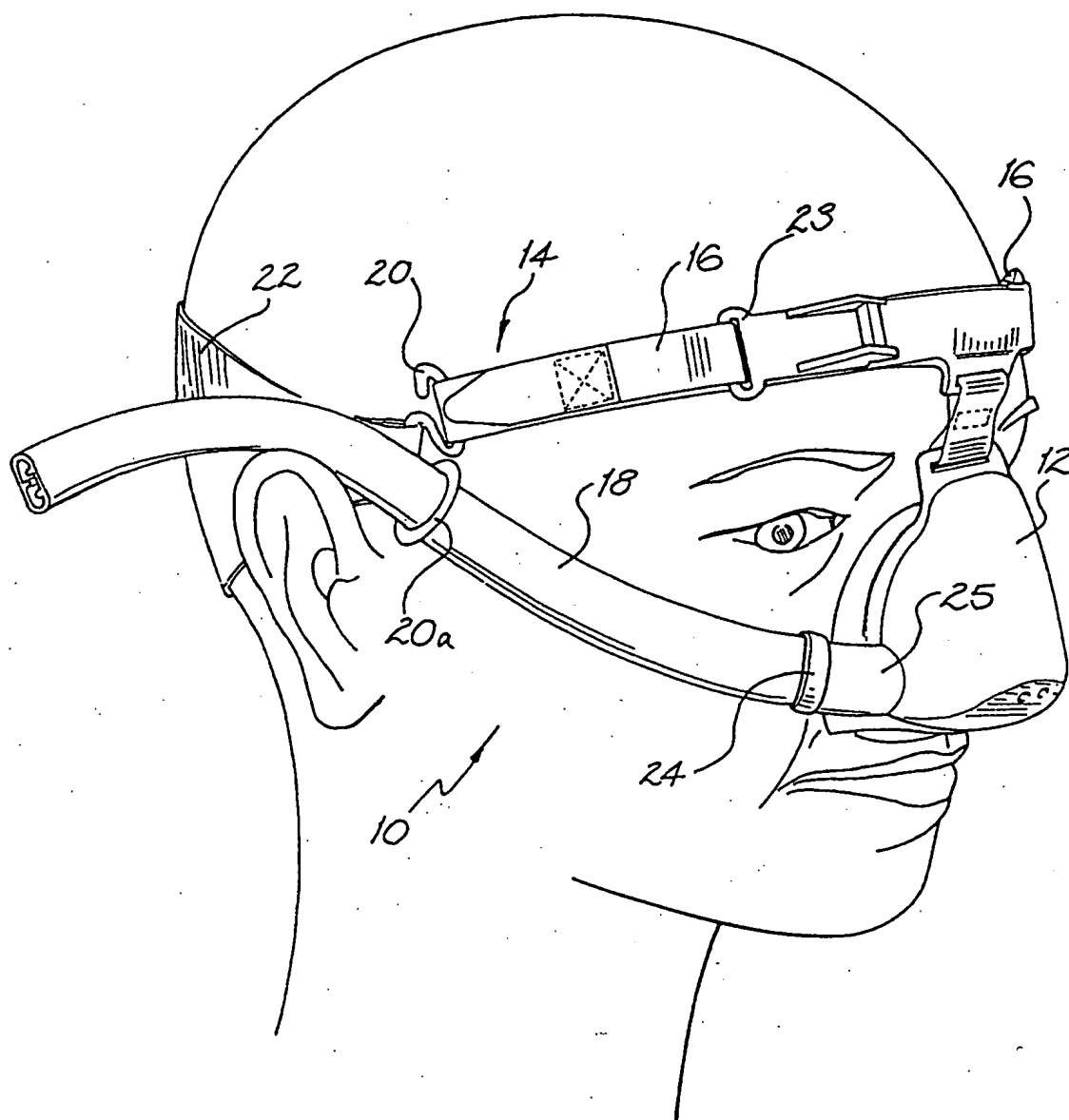


FIG. 1

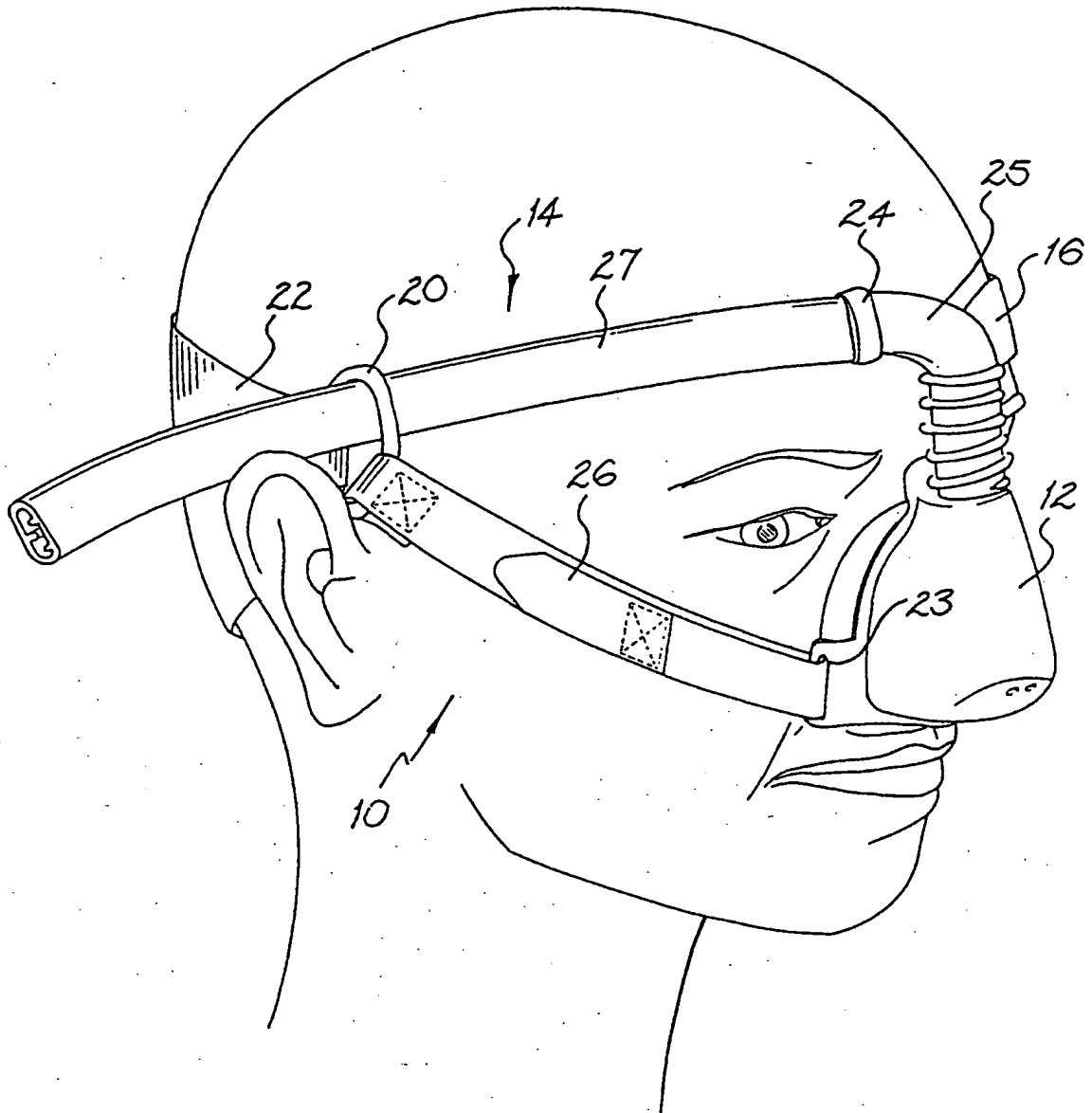


FIG. 2

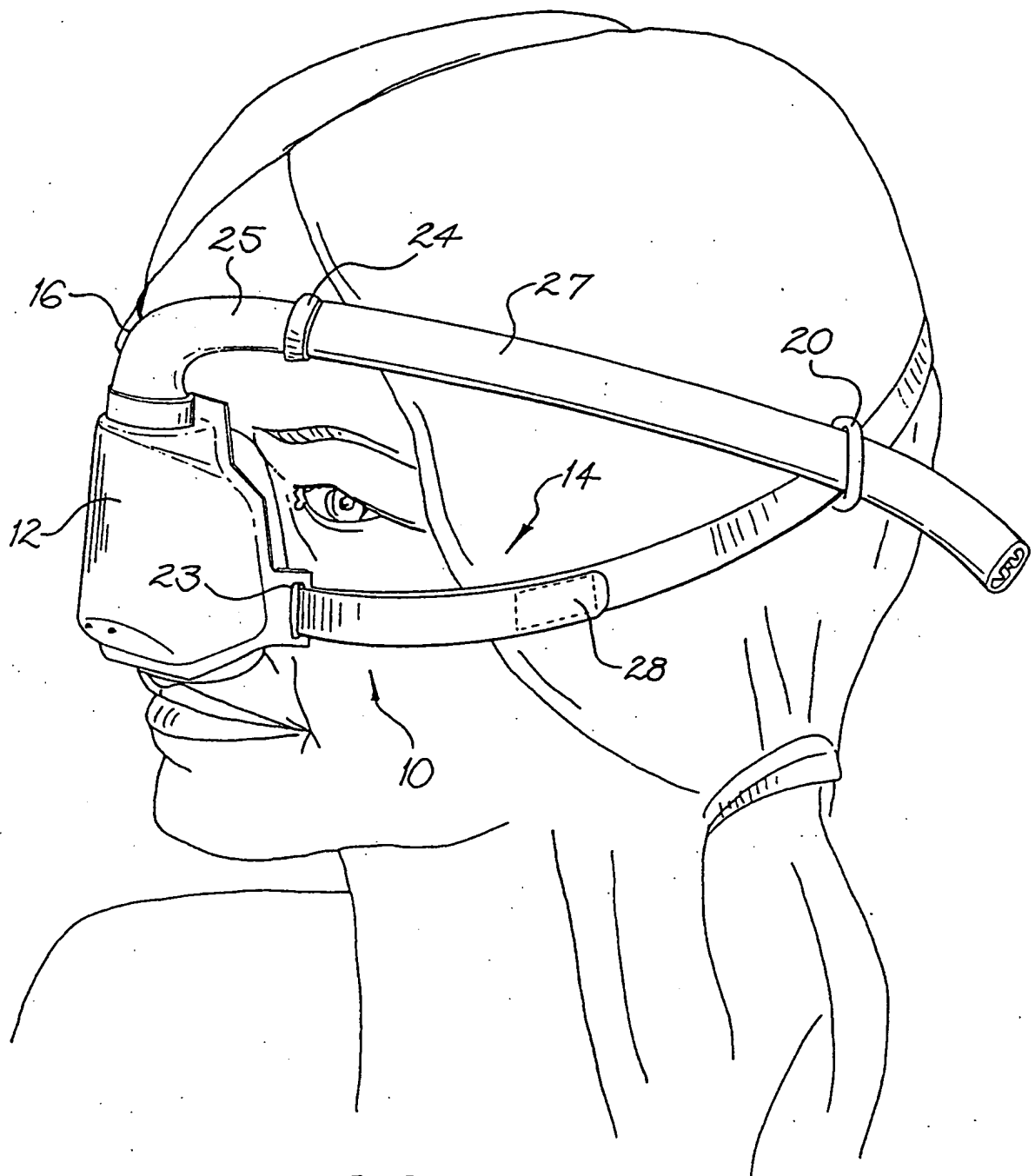
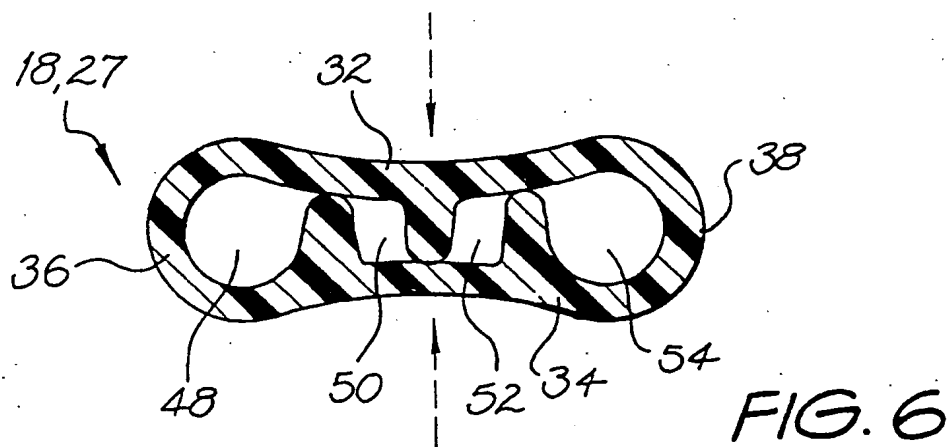
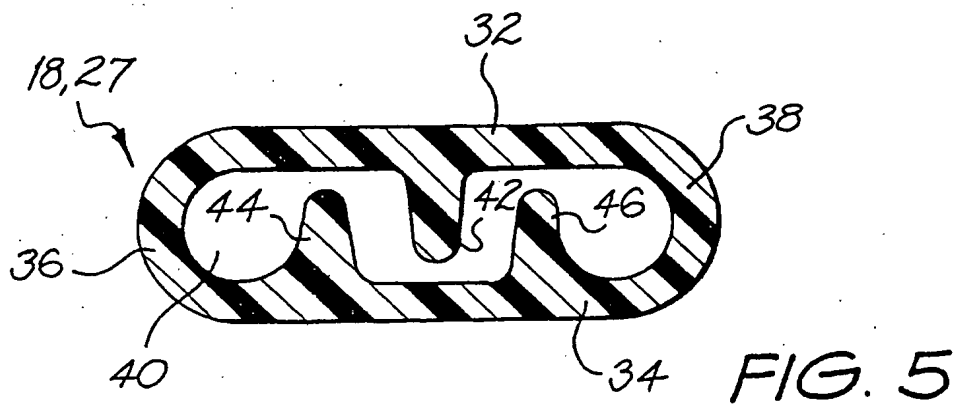
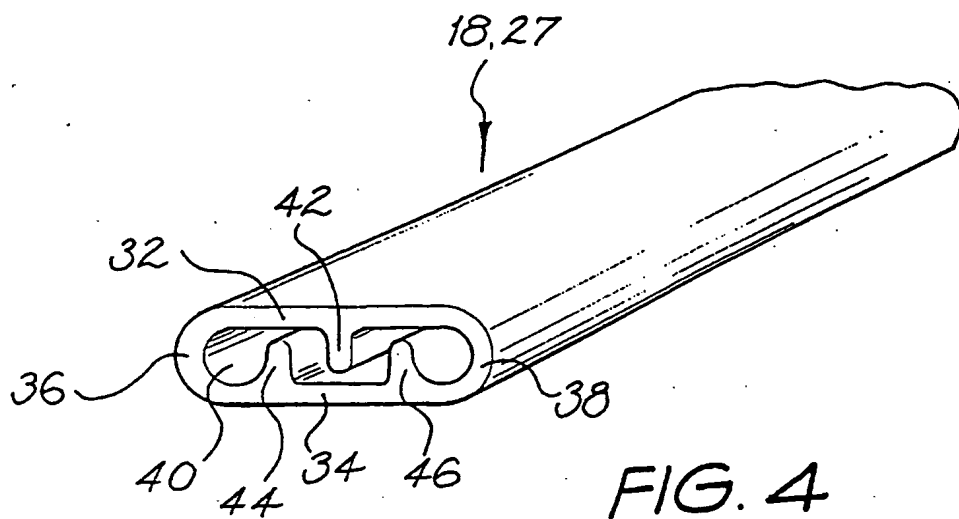


FIG. 3



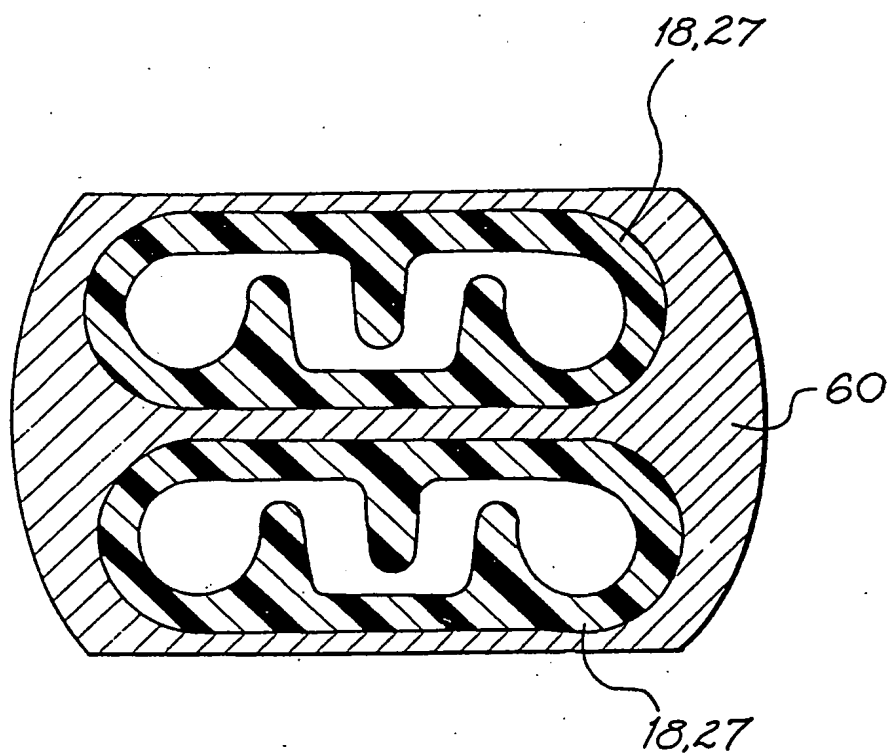


FIG. 7

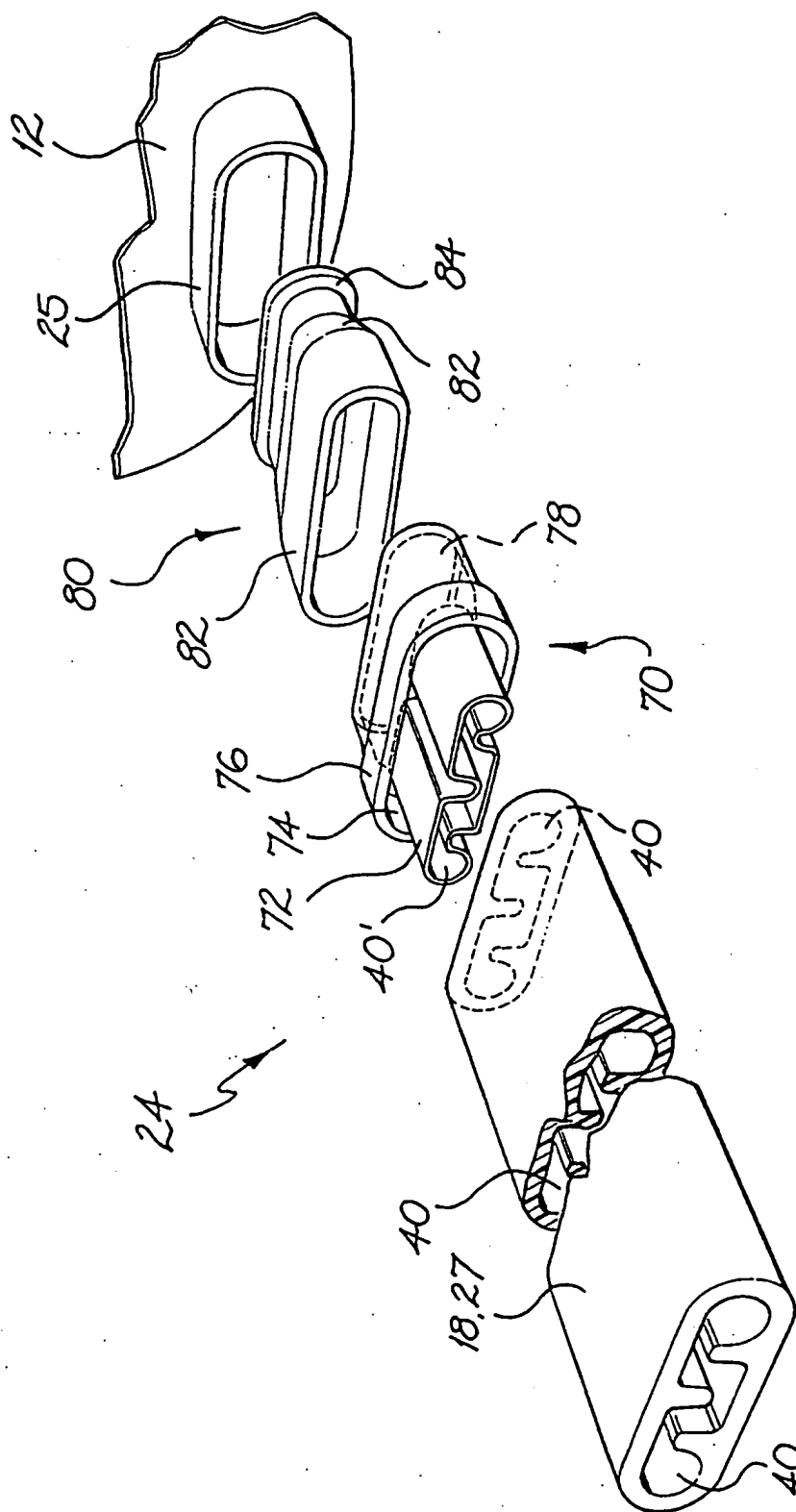


FIG. 8

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 97/00822

A. CLASSIFICATION OF SUBJECT MATTER		
Int Cl ⁶ : A61M 16/06		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols) A61M 16/06		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched AU IPC as above		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DERWENT Mask:, nasal: or nose:, breath:, respira: or air: strap JAPIO		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 94/02190 A (Geisen et al) 3 February 1994 Figures 2 and 3	1
A	US 5488948 A (Dubruille et al) 6 February 1996 Figure 1	
A	US 5431158 A (Tirota) 11 July 1995 Figure 1	
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex		
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Date of the actual completion of the international search 30 January 1998		Date of mailing of the international search report 19 FEB 1998
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INTERNATIONAL SEARCH REPORT

International Application No.
PCT/AU 97/00822

C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4848366 A (Aita et al) 18 July 1989 Figure 1	
A	US 4412537 A (Tiger) 1 November 1983 Whole document	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No.
PCT/AU 97/00822

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report			Patent Family Member	
WO	9402190	DE	4307754	
US	5488948	EP	645164	FR 2710272
				END OF ANNEX